K002490

OCT - 3 2000

Fonar Corporation
110 Marcus Drive
Melville, New York 11747-4292

August 9, 2000

510(k) Summary

Submitter Information:

Company: FONAR Corporation
Registration Number 2432211
110 Marcus Drive, Melville, New York 11747-4292

Contact: Luciano Bonanni Executive Vice President
Phone: (631) 694-2929 Fax: (631) 753-5150
E-mail: lbonanni@fonar.com

Device Designation:

Device Name: Indomitable Magnetic Resonance Imaging Scanner
Common Name: Magnetic Resonance Imaging Scanner (MRI Scanner)
Classification: System, Nuclear Magnetic Resonance Imaging (NMR/MRI)
Product Code: LNH (formerly 90JAM) Class: 2 Tier: 2
C.F.R. Section 892.1000 Classification Panel: Radiology

Applicable Performance Standards

On April 9, 1999, Intertek Services Corporation certified the Fonar Quality Management System to the standards EN ISO9001, BS EN9001 and ANSI/ASQC Q9001-1994. On May 25, 1999, the Fonar Quad 12000 was awarded the CE certificate and the quality system was certified to the additional standard of EN46001:1997. Our manufacturing systems were tested against the standards IEC 60601-1 (1988), IEC 60601-1-1 (1992-06), IEC 60601-1-2 (1993-04), IEC 60601-2-32 (1994-03) and IEC 60601-2-33 (1995-07). As part of the design/testing process for new products, Fonar utilizes the NEMA standards MS-1 through MS-8 for measuring performance and safety parameters (the standard MS-6 is not applicable to this submission). Images exported from the system utilize the DICOM standard.

Predicate Devices:

The magnet used in the Indomitable system is substantially equivalent to the 6,000 Gauss (0.6T) Fonar 360° magnet and the 6,000 Gauss (0.6T) QUAD 12000 magnetic resonance imaging scanners. These magnets were selected as the predicate devices because of their similarities in intended use, magnetic field orientation, construction methods, materials and operating characteristics. They remain substantially equivalent to their previously approved forms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2000

Luciano Bonanni
Executive Vice President
FONAR Corporation
110 Marcus Drive
Melville, NY 11747-4292

Re: K002490
Indomitable Magnetic Resonance Imaging Scanner
Dated: August 9, 2000
Received: August 14, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Bonanni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

Applicant: FONAR CORPORATION
510(k) Number (if known): K002490
Device Name: Indomitable Magnetic Resonance Imaging Scanner

Indications For Use:

The Indomitable Magnetic Resonance Imaging System is indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast upon NMR parameters [hydrogen nuclei concentration and flow velocity, T1 (spin-lattice relaxation time) and T2 (spin-spin relaxation time)]. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

WARNING: This device is limited by U.S. Federal law to investigational use for indications not in the indications statement.

Under the requirements of the law, the non-indicated applications can be used only under an Institutional Review Board approved protocol for a non-significant risk device or an Investigational Device Exemption application approved by the FDA for a significant risk device The procedures to be followed, under the sponsorship of FONAR Corporation, are determined by the current guidelines established by the FDA, which should provide the IRB with sufficient guidance to determine the level of risk for a MRI device.

WARNING: U.S. Federal law restricts the sale, distribution and use of this device by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seyram

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002490

Prescription Use ✓
(Per 21 CFR 801.109)